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TITLE: The San Francisco HIV Post-Exposure Prevention (PEP) Project

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BACKGROUND: The San Francisco Post-Exposure Prevention Project (PEP) is a feasibility study of HIV antibody testing, risk reduction counseling, and antiretroviral medications following high risk sexual or injection drug use (IDU) exposures. Outcomes include evaluation of 1) baseline demographic characteristics, risk behaviors, and source HIV status/risk status in persons seeking PEP, 2) changes in sexual behavior at six and twelve months; and 3) medication toxicities.

METHODS: Subjects are enrolled within 72 hours of unprotected receptive or insertive anal or vaginal intercourse, receptive oral intercourse with ejaculation, or sharing of IDU equipment. HIV antibody testing and safety labs are performed at baseline and weeks 4, 26 and 52. Risk reduction counseling is provided at each study visit, with a structured 5 session protocol utilized in the first 5 weeks. The number of sexual partners and unprotected sexual acts are assessed at baseline, 6 and 12 months. The principle outcome is the change in the number of partners with whom the index had unprotected sex.

RESULTS: Between October 1997 and April 1999, 436 index subjects enrolled at three sites with a total of 492 exposure episodes. 48 source partners have also enrolled. Follow-up will continue through April 2000. Updated data in the following areas will be presented: baseline demographics, baseline and follow-up risk behavior, source HIV status and risk characteristics, medication course, subjective and laboratory toxicities, and retention.

CONCLUSION: PEP medications and risk reduction counseling have been successfully offered and accessed by individuals in San Francisco following high risk sexual and IDU exposures to source partners who are at significant risk for HIV infection. Medication adherence and follow-up have been excellent. High levels of subjective toxicity have been reported. This study is not an efficacy study and we will not be able to determine the protective effect of post-exposure prophylactic antiretroviral medications in preventing the transmission of HIV-1. We will be able to evaluate the effect on subsequent risk behaviors in this high-risk population when all the follow-up data have been collected and analyzed.

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